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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/501,643 | 02/10/00 | SKLAR | D UNME-0070-1 |

Ajay A jagtiani
Jagtiani & associates
1037*9-B Democracy Lane
Fairfax VA 22030

HM22/0913

EXAMINER

GABEL, G

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

9
09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/501,643

Applicant(s)

SKLAR ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 28-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 6/21/01, in Paper No. 7 is acknowledged and has been entered. Claims 1 and 13-14 have been amended. Currently, claims 1-27 are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

2. In light of Applicant's amendment and arguments, the rejection of claims 1-27 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5, 7-12, 15-19, and 26-27 stands rejected under 35 U.S.C. 102(b) as being anticipated by Saros et al. (US 4,853,336) for reason of record.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 4, 6, 13-14, and 20-24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Saros et al. (US 4,853,336) in view of Kercso et al. (US 6,132,685) for reason of record.

5. Claims 25 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Saros et al. (US 4,853,336) in view of Kercso et al. (US 6,132,685) and in further view of Farrell et al. (US 5,788,927) for reason of record.

6. Claims 1-3, 8-12, 15-19, and 26-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (US 6,150,180) in view of Hach et al. or Trinel et al. (US 4,116,631) for reason of record.

Response to Arguments

7. Applicant's arguments filed 6/21/01 have been fully considered but they are not persuasive.

A) Applicant argues that Saros fails to teach or suggest a means for selectively analyzing a plurality of samples in a flow cytometer such as recited in claim 1 because a flow cytometer is an inherently different pressurized detector device that has to be pumped against pressure. The instant invention uses a peristaltic pump to deliver samples to a flow cytometer and Saros does not teach or suggest use of a peristaltic pump.

In response, the flow analyzer for selectively analyzing a plurality of samples taught by Saros appears to disclose the same components as the flow cytometer recited in claim 1 which therefore qualifies its function as being able to perform cytometric measurements. Specifically, the flow analyzer recited in claim 1 does not recite a peristaltic pump to effect sample delivery for a homogeneous continuous sample flow and therefore, does not exclude use of pressurized pump. Also, contrary to Applicant's contention, Saros, indeed, disclose a peristaltic pump in column 6, lines 52-55. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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B) Applicant argues that Kercso and Farrell in combination with Saros does not suggest the claimed invention because Kercso and Farrell do not overcome the deficiency of Saros.

In response, the flow analyzer for selectively analyzing a plurality of samples taught by Saros appears to disclose the same components as the flow cytometer recited in claim 1 which therefore qualifies its function as being able to perform cytometric measurements. Specifically, the flow analyzer recited in claim 1 does not recite a peristaltic pump to effect sample delivery for a homogeneous continuous sample flow and therefore, does not exclude use of pressurized pump. Also, contrary to Applicant's contention, Saros, indeed, disclose a peristaltic pump in column 6, lines 52-55. It is, therefore, maintained that Saros discloses the rejected claims as currently recited and the combination of Saros with both Kercso and Farrell suggests the flow cytometer in the claimed invention.

C) Applicant argues that Parce discloses a high throughput assay system that fails to teach or suggest a means for introducing a separation gas between each sample to selectively analyze each sample in a flow cytometry. Applicant contends that Parce uses electronic pipettors to introduce samples and a plug of low ionic spacer fluid separates the samples in the system whereas a flow cytometer is an inherently different pressurized detector device that has to be pumped against pressure. The instant invention uses an autosampler, air bubbles keep the samples separate and a peristaltic pump delivers samples to a flow cytometer.

Applicant also argues that Hach only teaches an automatic analyzer for sampling impure water including a means for moving samples and a means for introducing separation gas to separate the samples whereas the present invention utilizes separation gas to maintain identity of multiple samples being analyzed in a flow cytometer.

Applicant further argues that Trinel teaches a continuous flow analyzer for microbiological analysis of liquid media including a means for flowing a plurality of samples but fails to teach a means for introducing a separation gas between each sample to effect separation therebetween for selectively analyzing the samples in a flow cytometer. Applicant therefore contends that Trinel fails to overcome the deficiencies of Parce.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Parce et al. disclose flow analyzer for high throughput screening and detection of particles or biomaterials in a plurality of samples to analyze for test compounds including an autosampler, i.e. electropipettor or injector, for introducing the samples from a source. The movement of the samples and test compound mixtures may be carried out using integrated or external peristaltic pumps and valves, i.e. micropumps and microvalves. Flow of individual samples or test compounds are separated by the spacer buffer. Hach et al. was incorporated therewith for a disclosure

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of an automated analyzer that includes a pump and a means for periodically injecting separation gas to separate liquids. On the other hand, Trinel et al. was also incorporated with Parce for the disclosure of an automatic flow analysis apparatus wherein the spacing between samples and decontamination solution are effected by segments of an separation inert gas.

One of ordinary skill in the art at the time of the instant invention would have a reasonable expectation of success in substituting air to separate individual samples for analysis in flow analyzers or microfluidic systems such as taught by Hach or Trinel for the spacer buffer or separation fluid in the flow channels taught by Parce because Hach and Trinel specifically suggested that separation gas, when incorporated into proper tubing materials and parameter requirements, provides adequate separation between sequential samples so as to prevent contamination or carry-over therebetween.

Further, the flow analyzer for selectively analyzing a plurality of samples as suggested by the combined disclosures of Parce in view of Hach or Trinell appears to suggest the same components as the flow cytometer recited in claim 1 which therefore qualifies their combined function as being able to perform cytometric measurements. Specifically, the flow analyzer recited in claim 1 does not recite a peristaltic pump to effect sample delivery for a homogeneous continuous sample flow and therefore, does not exclude use of other, i.e. pressurized pump. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

D) Applicant submitted a 1.132 declaration to set forth that the material requirements and parameters for the tubing used in the instant invention provides improved sample separation results in comparison to the systems taught by the prior art of record.

In response, it is maintained that parameter requirements in flow systems or microfluidic channels such as inner diameter of 0.01 to 0.03 inches and wall thickness of 0.01 to 0.03 inches are all result effective variables which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum parameter of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since the prior art teaches that flow analysis system requirements often vary according to the samples, types, and flow requirements thereof; absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable parameters and requirements of the methods disclosed by the prior art by normal optimization procedures.

8. For reasons aforementioned, no claims are allowed.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 4:00 PM and alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gailene R. Gabel
Patent Examiner
Art Unit 1641

9/10/01


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

09/10/01